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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,079	06/22/2001	Signe Erickson Varner	55821 (71699)	6574

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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,079	VARNER ET AL.	
	Examiner	Art Unit	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-35,38,41-47 and 59-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-35,38,41-47 and 59-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 23-30,32,33-40,42-44,47-52,54,55,58-65,67-69, and 72-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Paques et al. (US Pub 2003/0171722).

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gauge (0053) allowing the puncture location to self-seal and having a flexible plastic tube therein (0087) to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion (0039) by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2, 3 and paragraph [0105]-[0113]).

3. Claims 23-35, 38, 41-47, and 59-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Josephberg (USPN 5,989,262).

Josephberg discloses a method for treating an eye with a device comprising a piercing member with an outer diameter less than 25 gauge allowing the puncture location to self-seal and having a flexible plastic tube therein to administer a therapeutic substance to the eye. The device is used to treat conditions

such as vascular occlusion by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2, 3 and entire reference).

4. Claims 23-35, 38, 41-47, and 59-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Trese (USPN 6,428,553).

Trese discloses a method for treating an eye with a device comprising a piercing member with an outer diameter less than 25 gauge allowing the puncture location to self-seal and having a flexible plastic tube therein to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2, 3, 4, 5, 6 and entire reference).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31,45,46,56,57,70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of del Cerro et al (USPN 5,409,457).

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach withdrawal of fluid from the eye.

Del Cerro et al. teaches a device comprising a tip for penetrating the subretinal region of the eye to deliver a therapeutic agent or withdraw fluid from the eye (column 4, line 31).

It would have been obvious to one skilled in the art at the time of the invention to withdraw fluid from the eye in order to reduce the pressure in the eye, as well as to deliver therapeutic fluid to treat the disease or injury both actions possible with the syringe connected to the device of Paques.

6. Claims 41, 53, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of Bowman et al. (USPN 6,378,526)

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach the delivery of steroids.

Bowman et al., teaches a device for delivery of a therapeutic agent such as steroids, genetic material, or pharmaceuticals to the eye.

It would have been obvious to one skilled in the art at the time of the invention to deliver agents such as steroids to the eye depending on the needs of the patient.

Response to Arguments

7. Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive.

8. With regards to a method of inserting a device into the eye by piercing the eye with the needle and then followed by inserting the piercing member and the cannula into the eye is taught in Paques paragraph [0108]. In paragraph [0108],

> 108] Under either local or general anesthesia, a conventional pars-plana approach with vitrectomy with separated infusion is performed. The instrument of FIGS. 1-3 is used to introduce the needle 4 and the distal end 14*d* of the optical fiber 14 into the eye through a sclerotomy. The distal extremity of the needle is brought coaxially close to the retinal vein, approximately 500-2000 microns from the optic disc. The site of penetration of the vein can be nasal, temporal, inferior or superior according to the clinical and anatomical features of the fundus vessels of the eye to be treated. The retinal vein is then penetrated with the sharp distal end of the needle 4 (FIG. 3), which is preferably 30-120 microns diameter. A fibrinolytic agent, such as recombinant tissue plasminogen activator (rTPA) or streptokinase, is

9. then infected to dissolve the vein thrombus.

10. The instrument is introduced the needle and cannula into the eye through a sclerotomy (which is an incision in the sclera of the eye). Therefore, the needle and cannula must pierce the eye as claimed in the prior art, since the needle must travel through the eye. Also the needle and cannula treat the eye by a fibrinolytic agent, which can be seen in the above paragraph.

11. The 112 Rejections are withdrawn because of the remarks by the applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
June 27, 2005

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700